4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1105]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Hazard Analysis and Critical Control Point Manuals for Operators and Regulators of Retail and Food Service Establishments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with FDA's technical assistance reference manuals provided to State, local, territorial, and tribal jurisdictions, and other Federal Agencies to interpret and promote the application of Hazard Analysis and Critical Control Point (HACCP) principles to reduce the risk of foodborne illness in the operation of retail and food service establishments.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on re spondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Voluntary Hazard Analysis and Critical Control Point Manuals for Operators and Regulators of Retail and Food Service Establishments (OMB Control Number 0910-0578)--Extension

HACCP principles are designed to reduce the occurrence of foodborne illness risk factors through preventive controls. FDA has developed two technical assistance reference manuals that interpret and promote the application of HACCP principles to reduce the risk of foodborne illness in the operation of retail and food service establishments.

The responsibility and authority for regulating retail and food service establishments lie primarily with State and local governments. Officials in State, local, territorial, and tribal agencies inspect these food facilities, license establishments, issue permits, and enforce their State or local government's laws and regulations. FDA's Retail Food Protection Program provides assistance to the more than 3,000 State and local government agencies that regulate the retail food industry nationally. The primary objective of the Retail Food Protection Program is to prevent foodborne illness at the retail level of the food industry by directing activities toward promotion of effective State and local regulatory programs. FDA provides assistance to State, local, territorial, and tribal regulatory jurisdictions through multiple means including, but not

limited to, training and technical assistance. Authority for providing such assistance is derived from section 311 of the Public Health Service Act (42 U.S.C. 243). In addition, FDA's mission under section 903(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(b)(2)(A)) includes ensuring that foods are safe, wholesome, and sanitary, and section 903(b)(4) of the FD&C Act directs FDA to cooperate with food retailers, among others, in carrying out this part of its mission.

The first manual, entitled "Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments" (Operator's Manual) (available at http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACCPPrinciples/Operators/default.htm), provides operators of retail and food service establishments a roadmap for developing a food safety management system based on HACCP principles. Food safety management systems allow establishment operators to take a proactive role in ensuring that the food served or sold in their establishment is safe. Rather than responding to a foodborne illness when it occurs, they can prevent it by taking active steps to eliminate, prevent, or reduce to an acceptable level food safety hazards that may cause someone to become sick or injured.

The second manual, entitled "Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems" (Regulator's Manual) (available at http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACCPPrinciples/Regulators/default.htm), provides State, local, territorial, and tribal regulatory authorities with a model for prioritizing inspections using a risk-based approach. The Regulator's Manual

provides a roadmap for evaluating retail and food service establishments based on the application of HACCP principles.

FDA developed the manuals as technical assistance reference resources for regulators and operators to help reduce the risk of foodborne illness. There is no Federal requirement that retail and food service establishments implement food safety management systems based on HACCP principles. State, local, territorial, and tribal regulatory authorities decide whether to require food safety management systems in the operation of retail and food service establishments. Regulators and operators will not submit information to FDA based on these manuals.

Regulators and retail and food service operators use the manuals as technical assistance reference resources. The Regulator's Manual contains information, recommendations and model documents for State, local, territorial, and tribal regulators who wish to develop practices for risk-based inspections of retail and food service establishments based on the application of HACCP principles. The Operator's Manual contains information, recommendations and model documents for operators of retail and food service establishments who wish to develop and/or validate the practices used in a food safety management system based on HACCP principles.

Description of Respondents: The respondents are State, local, territorial, and tribal regulatory jurisdictions and operators of retail and food service establishments in the United States. Respondents are from both the public sector (State, local, territorial, and tribal governments) and the private sector (for-profit businesses).

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden[1]

Activity	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
Reference of Technical Assistance Manuals by Operators	25,000	1	25,000	0.2 (12 minutes)	5,000
Reference of Technical Assistance Manuals by Regulators	1,500	1	1,500	0.25 (15 minutes)	375
Total					5,375

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of operator recordkeepers estimated in column 2 of Table 1 is based on FDA's goal to have 50,000 (1/2 of 1 percent) of the approximately one million U.S. retail and food service operators implement the recommendations outlined in the two manuals, as estimated in 2009 (73 FR 77721, at 77722). FDA's estimate of the total number of retail and food service establishments is based on numbers obtained from the two major trade organizations representing these industries, the Food Marketing Institute and the National Restaurant Association. Gathering reference material to develop and/or validate food safety management system practices is a one-time burden. We assume that those 50,000 operators have utilized FDA's technical assistance manuals to the degree that they chose to do so over the past 3 years and over the next 3 years will only need to reference these manuals on an as-needed basis. FDA estimates that, annually, approximately one half of the operators, 25,000, will choose to reference FDA's information, recommendations or model documents.

The number of regulator recordkeepers estimated in column 2 of Table 1 is based on FDA's estimate that there are approximately 3,000 State, local, territorial, and tribal regulatory jurisdictions. Gathering and reviewing reference material to develop practices for risk-based

inspections of retail and food service establishments based on HACCP principles is a one-time burden. We assume that those 3,000 regulatory jurisdictions have utilized FDA's technical assistance manuals to the degree that they chose to do so over the past 3 years and over the next 3 years will only need to reference these manuals on an as-needed basis. FDA estimates that, annually, approximately one half of the regulatory jurisdictions (1,500) will choose to reference FDA's information, recommendations or model documents.

The hours per record estimated in column 2 of Table 1 are based on FDA's experience with similar technical assistance materials offered by the Agency. FDA estimates that over the next 3 years regulators and operators will only need to reference these manuals on an as needed basis. We estimate that it will take an operator with a specific need for information approximately 12 minutes (0.2 hour) to gather and record the data from the manuals. We estimate that it will take a regulator with a specific need for information approximately 15 minutes (0.25 hour) to gather and record the data from the manuals.

The total recordkeeping burden of the technical assistance manuals is 5,375 hours, as shown in Table 1.

Dated: November 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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